

HUBERT DORN ET AL.
USSN 09/780,646
Reply to Office Action dated January 26, 2004
Amendment Dated July 26, 2004

CONDITIONAL PETITION FOR EXTENSION OF TIME

If entry and consideration of the amendments above requires an extension of time, Applicants respectfully request that this be considered a petition therefor. The Commissioner is authorized to charge any fee(s) due in this connection to Deposit Account No. 14-1263.

ADDITIONAL FEE

Please charge any insufficiency of fees, or credit any excess, to Deposit Account No. 14-1263.

REMARKS

Applicants respectfully request reconsideration and allowance of this application in view of the amendments above and the following comments.

New claims 16 and 17 have been added, which are, respectively, drawn to a non-systemic method of treating fleas on a dog or cat and of treating lice on a human. Applicants do not believe that either of claims 16 or 17 introduces any new matter. An early notice to that effect is earnestly solicited.

Claims 10-15 were rejected under 35 USC § 112, first paragraph, as being beyond the enabling disclosure. The Examiner takes the position that the data of record are insufficient to

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establish that the benefits observed are not, in fact, systemic at least in part. Applicants respectfully disagree.

There are three declarations currently of record:

- 1) A first declaration of Dr. Hubert Dorn executed on August 4, 1996;
- 2) A second declaration of Dr. Dorn executed on December 10, 1996; and
- 3) A declaration of Dr. Olaf Hansen.

If the Examiner does not have any of these declarations in the file, he is respectfully requested to telephone the undersigned at telephone number (212) 808-0700 so that another copy can be provided.

Applicants would direct the Examiner's attention to page 22 of the Dorn Declaration executed on August 4, 1996. There in the second paragraph it is explained in no uncertain terms why the benefit observed must be a non-systemic action. Basically, the benefit is not observed on parts of the skin of the animal that have been shorn, shaven and cleaned. If the benefit were due to a systemic effect, then shearing, shaving and cleaning should have no effect whatsoever since the active agent would be transported to the site by the blood system, and such transport could not be influenced by shearing, shaving and cleaning the animal. The fact that shearing, shaving and cleaning eliminates the benefit means that the benefit observed is due to a non-

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systemic action.

Dr. Dorn explains in the second paragraph on page 22 of the Declaration executed on August 4, 1996, that:

“Distribution is *not* the result of a systemic mode of action via passing through the skin, passing into blood circulation system and oral uptake by the blood sucking flea. *This is demonstrated* by the fact that Imidacloprid has nearly no effect upon fleas on skin parts which have been shorn and shaven and cleaned after treatment. Imidacloprid however has full activity on skin parts which have been shorn and shaven *but not cleaned* after treatment or which remained as they were after treatment.”

[Emphasis added.]

Respectfully, the Examiner’s unsupported skepticism must give way to these unequivocal statements of Dr. Dorn that the distribution observed cannot be the result of a systemic mode of action. The Examiner simply must accept that a non-systemic mode of action is possible with this class of compounds. Having accepted that a non-systemic mode of action is possible with this class of compounds, the Examiner is without any reasonable basis to question the enablement in the present case. *In re Marzocchi et al.*, 169 USPQ 367, 369 (CCPA 1971).

The Examiner’s statement that the “disclosure is fatally flawed” is at once at odds with the declaration evidence of record and the “full faith and credit” requirement. The instant

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disclosure is identical with that of U.S. Patent No. 6,232,328. The examiner handling that application determined that enablement was satisfied based on the same declaration evidence now urged before the present Examiner. The Examiner is respectfully requested to give full faith and credit to the prior determination of the prior examiner, and to reconsider and withdraw this rejection.

Claims 10 and 12-15 were rejected under 35 USC § 103(a) as being obvious over Wolf et al. ("Wolf"), EP 0 285 985. In response, Applicants point out that this rejection is not made against claim 11. Applicants believe that the other issues respecting claim 11 have been overcome. Therefore, Applicants seek an early notice that at least claim 11 is allowable in substance.

With respect to the rejected claims, the Examiner states "[w]e find no difference here, and there, as to the systemic or non-systemic activity, except for the wherein-thus, there is no difference in fact, as applicant alleges, but does not show." In response, Applicants point out that they have explained above where in the record the Examiner can find evidence that the benefit achieved using the claimed class of compounds clearly is non-systemic and not systemic. Thus, Applicants have shown non-systemic effects, and have not merely alleged them.

Second, according to *Manual of Patent Examining Procedure* ("MPEP") § 2143:
"To establish a *prima facie* case of obviousness, three basic criteria

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must be met. First, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings. Second, there must be a reasonable expectation of success. Finally, the prior art reference (or references when combined) must teach or suggest all the claim limitations."

[Emphasis added.] The Examiner is without authority to ignore any claim limitation—including those in a "wherein" clause. In the instant case, the "wherein" clause constitutes a true limitation since it restricts the result that the method must achieve, and does so in the body of the claim, not merely in the preamble thereof. There is no legal basis for ignoring this limitation, and Applicants respectfully submit that the Examiner must give it the proper weight. Thus, the present claims cannot be *prima facie* obvious unless the cited prior art teaches or suggests a non-systemic mode of action is desirable and can be achieved.

Third, the prior art, which includes WO 93/24002, of record, established that only systemic application is suitable for compounds of the type involved here. Thus, Applicants' discovery of the effectiveness of non-systemic application flies in the face of the prejudice against such application as clearly evident in the prior art. That Applicants proceeded in the face of the prior art, and accomplished the present invention, is evidence of an inventive contribution, which is, thus, deserving of patentability.

Fourth, the Examiner nowhere disputes the teachings of WO 93/24002, or that a systemic mode of action is taught in the prior art to be required for the class of compounds used instantly.

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The Examiner's difficulty apparently was with the lack of a showing by Applicants that the class of compounds used instantly worked by a non-systemic mode of action to the exclusion of any systemic mode of action. However, Applicants have explained above where in the record such a demonstration can be found. The beneficial effect observed was found to be dependent on shearing, shaving and cleaning, which would not have been the case if the beneficial effect was produced systemically. The fact that the beneficial effect observed was found to be dependent on shearing, shaving and cleaning means that the beneficial effect is produced non-systemically, which, therefore, distinguishes the present invention from what the prior art clearly teaches is necessary for a successful result.

The Examiner has not established the well known state of the prior art to be other than Applicants have set forth in the preceding paragraph. Therefore, the present rejection cannot be maintained simply by showing that the cited prior art mentions dermal application. Instead, the Examiner must show that the prior art teaches or suggests non-systemic application specifically. Applicants submit that the cited reference nowhere teaches or suggests non-systemic application specifically. Consequently, the Examiner should reconsider and withdraw this rejection.

To the best of Applicants' knowledge, at the time the present invention was made, persons skilled in the art would not have considered the non-systemic application of the compounds of the present claims in order to control ectoparasitic insects on animals or humans. Such persons also would not have expected their surprisingly high efficiency over a long-term.

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While referring to a different type of compounds, *but of the same class of agonists or antagonists of the nicotinergic acetylcholine receptors of insects*, the introductory part of WO 93/24002, of record here, as noted above, accurately reflects the thinking of persons skilled in the art at the time the present invention was made. Although dermal application of active ingredients to animals was, of course, known in general principle, WO 93/24002, as noted above, discloses that only systemic application is suitable for the compounds disclosed therein. Thus, non-systemic application was clearly thought to be unsuitable for compounds such as are described in WO 93/24002.

The same expectation applied to the specific compounds required by the instant claims. The prevailing thought was that systemic application must be achieved, even if the application was a dermal application. Nothing in the cited references suggests otherwise.

EP-A-0 285 985 lists virtually all known application forms for veterinary medicine. See page 7, lines 31 ff, of the German text. However, as all of these application forms are listed without specific comments or preferences, the document does not surmount the prejudice in the art that systemic application must be achieved. Consequently, the reference would not have led persons skilled in the art to carry out dermal application in such a way as to achieve non-systemic application, as presently claimed.

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"Laundry lists," of the type set forth in EP-A-0 285 985, have been held in some instances not to constitute a written description of an embodiment sufficient to support an anticipation rejection under 35 USC § 102. *See, e.g., In re Wiggins et al.*, 179 USPQ 421, 425 (CCPA 1973).

In further support of Applicants' position, Applicants previously supplied a partial translation of the paragraphs of EP-A-0 285 985 upon which the Examiner relies. Although the reference does mention dermal application, the reference is silent as to the achievement of non-systemic control. Consequently, EP-A-0 285 985 would not, in fact, have suggested non-systemic application to persons skilled in the art.

To the extent that non-systemic dermal application is considered to be an obvious choice of administration method, Applicants would request that the Examiner again reconsider the data of record. The data show that the results achieved with non-systemic dermal application are superior even to those obtained with oral treatment. There is absolutely nothing in the cited prior art that teaches or suggests the superiority of non-systemic dermal application over oral treatment. Consequently, the data in the declarations of record are proof of a surprising and unexpected result, which is, thus, objective evidence of nonobviousness.

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In view of the foregoing, Applicants respectfully request that the Examiner reconsider and withdraw this rejection. An early notice that this rejection has been reconsidered and withdrawn is earnestly solicited.

Claims 10-15 were rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-8 of U.S. Patent No. 6,232,328. In response, Applicants point out that restriction was required during the prosecution of grandparent application Serial No. 08/925,372, which matured into the cited U.S. Patent No. 6,232,328. The subject matter issued in the grandparent patent was indicated to be patentably distinct to the instantly claimed subject matter, and this divisional application was filed as a result of that indication. Consequently, the Patent Office cannot now turn around and find obviousness-type double patenting to exist over the same grandparent application. 35 USC § 121. Consequently, Applicants submit that this rejection is in error, and respectfully request that the Examiner reconsider and withdraw this rejection.

Claims 10 and 12-15 were rejected under 35 USC § 112, second paragraph, as being indefinite. According to the Examiner, the rejected claims lack any definition of Z. In response, Applicants point out that claim 10 quite clearly states that "A and Z together with the nitrogen and carbon atom to which they are bonded form a saturated heterocyclic ring having 6 ring members * * *." The other rejected claims incorporate this same definition of Z by their dependence on claim 10. Consequently, the Examiner is in error that the rejected claims lack a

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definition of Z. Accordingly, Applicants respectfully request that the Examiner reconsider and withdraw this rejection.

Applicants believe that the foregoing constitutes a bona fide response to all outstanding objections and rejections.

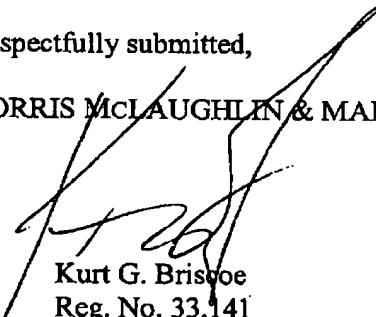
Applicants also believe that this application is in condition for immediate allowance. However, should any issue(s) of a minor nature remain, the Examiner is respectfully requested to telephone the undersigned at telephone number (212) 808-0700 so that the issue(s) might be promptly resolved.

Early and favorable action is earnestly solicited.

Respectfully submitted,

NORRIS MC LAUGHLIN & MARCUS, P.A.

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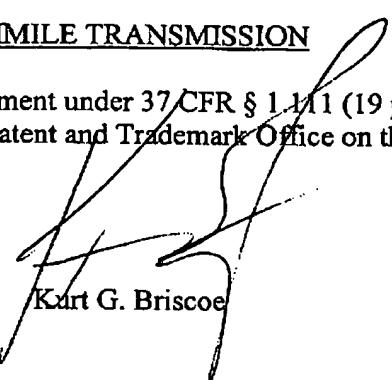
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CERTIFICATE OF FACSIMILE TRANSMISSION

I hereby certify that the foregoing Amendment under 37 CFR § 1.111 (19 pages total) is being facsimile transmitted to the United States Patent and Trademark Office on the date indicated below:

Date: July 26, 2004

By:


Kurt G. Briscoe